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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/693,577 | 10/23/2003 | Lilip Lau | PARCR 65971 | 1087 |

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| EXAMINER |
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GILBERT, SAMUEL G

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| ART UNIT | PAPER NUMBER |
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3736

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/693,577 | Applicant(s) LAU ET AL. ED | |
| | Examiner Samuel G. Gilbert | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 54-70 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/2/2004; 7/30/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 2/2/2004 has been considered.

The information disclosure statement filed 7/30/2004 has not been considered because only 2 digit years have been provided for most of the dates, four digit years are required to properly identify the dates. Further, at least the Lev, Maurice, M.D. has not been set forth with any date.⁶

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Every effort should be made to make the title unique with regards to the applicant's related applications.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "self-sizing", "self-attaching", self-tensioning", "self-adhering", and "self-expanding".

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

This application repeats a substantial portion of prior Application No. 10/693,577, filed 10/23/2003, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-58, 64 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the claims "self-sizing", "self-attaching", "self-tensioning", "self-adhering", and "self-expanding" are considered to be new-matter and not described in the originally filed specification as required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaraman (6,360,749) in view of Lau et al (6,517,570).

Jayaraman teaches a medical device, figures 6B, 7B, 7C, 8A, 8B-12 and 14 for treating the heart but does not teach the material including a plurality of hinge elements. Jayaraman does set forth that stent graft materials may be used. Lau et al. sets forth a plurality of embodiments of stent graft material formed by a plurality of hinge elements. Lau et al sets forth that the hinged elements provide the advantage of being foldable to be delivered intraluminally, kink-resistant and self-expanding. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the stent graft material taught by Lau et al. to be used for the stent graft material set

forth to provide the benefits as described above to the cardiac treatment device of Jayaraman.

Claim 55 - the hinge elements of Lau et al are "self-sizing" and the cardiac device of Jayaraman is adapted to extend circumferentially around the heart.

Claim 56 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are elastic which provide the capability of being "self-attaching". The examiner sets forth the following example; if the unstressed circumference of Jayaraman is smaller than the smallest circumference of the patients heart on which it is to be used then the jacket must be expanded to be placed on the heart the elasticity of the device would urge the device back to its unstressed condition which would make the device "self-attaching".

Claim 57 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are inherently "self-tensioning".

Claim 58 - Jayaraman is adapted to extend circumferentially around the heart and the hinge elements of Lau et al are elastic which provide the capability of being "self-adhering". The examiner sets forth the following example; if the unstressed circumference of Jayaraman is smaller than the smallest circumference of the patients heart on which it is to be used then the jacket must be expanded to be placed on the heart the elasticity of the device would urge the device back to its unstressed condition which would make the device "self-adhering".

Claim 59 – the compressive force of Jayaraman would be a function of the starting size of the jacket and the size of the heart on which it is used. It is the

examiner's position that any sized cardiac device taught by Jayaraman would generate a compressive force if the maximum circumference of the heart is smaller than the starting circumference of the cardiac jacket.

Claims 60 and 61 – the compliance is an inherent feature of the hinge elements set forth in figures 1A-1E of Lau et al.

Claim 62 – Jayaraman teaches strips that extend circumferentially around the heart.

Claim 63 – the material of Lau et al. provide a compressible to a low profile. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 64 - the hinge elements of Lau et al are "self-adjusting" and the cardiac device of Jayaraman is adapted to slide over the heart.

Claim 65 – the hinge elements of Lau et al are "self-expanding" see the title of Lau et al.

Claim 66 – Lau et al teaches the use of Nitinol, column 12 lines 31 and 32.

Claim 67 – the Nitinol hinge elements of Lau et al inherently have a deformed shape and a recovered shape.

Claim 68 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 69 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim 70 - the hinges of Lau et al. provide a compressible to a low profile, column 1 lines 9-16. The term minimally invasive delivery diameter is a broad term and almost anything delivered to the patient's heart could be considered to have a minimally invasive delivery diameter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54, 59, 68, 69, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartwell (2,278,926). Hartwell teaches a material formed of hinges as claimed, figure 1 or figure 2. The material can be cut to any desired size which is capable of being delivered to the heart minimally invasively. The cardiac device as claimed does not require a device that is capable of circumferentially surrounding the heart. Therefore the compressive force would be a function of how the material is attached to the heart which making it a functional limitation that does not impart any structural difference between the prior art device and the claimed invention.

Claims 54, 56, 58, 59, 62, 63, and 68-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Lederman et al (5,800,528).

Claim 54 – the applicant's attention is invited to the embodiment of Figure 4. The examiner is taking the loops –33– as a plurality of hinge elements because the interlinked loops provide a flexible connection wherein the rings may at least partially pivot around each other. The device is capable of being delivered minimally invasively.

Claim 56 – because the girdle of Lederman et al is capable of circumferentially surrounding the heart the jacket is considered “self-attaching”.

Claim 58 – because the girdle of Lederman et al is capable of circumferentially surrounding the heart the jacket is considered “self-adhering”.

Claim 59 – The compressive force applied by the girdle is a function of the size of the heart the girdle is being used on. If the maximum circumference of the heart the jacket is used on is the same as the maximum dimension of the girdle of Lederman et al would apply a compressive force on the heart of not more than 10 mm Hg.

Claim 62 – the Examiner is taking each circumferential ring of Lederman et al as a strip.

Claim 63 - the Examiner is taking each circumferential ring of Lederman et al as a strip. The device is compressible to a low profile.

Claims 68-70 – the device is compressible.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,702,732. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,682,474. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,663,558. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,595,912. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

Claims 54-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-74 of copending Application No. 10/865,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 54-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-62 of copending Application No. 10/314,696. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications to the scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 5150706 and 4,428,375 teach related surgical bags.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Samuel G. Gilbert', with a long horizontal flourish extending to the right.

Samuel G. Gilbert
Primary Examiner
Art Unit 3736

sgg